

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

2614 US0P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/018321

INTERNATIONAL APPLICATION NO.

PCT/JP00/03879

INTERNATIONAL FILING DATE

June 15, 2000

PRIORITY DATE CLAIMED

June 16, 1999

TITLE OF INVENTION

Benzazepine Derivative, Production and Use Thereof

APPLICANT(S) FOR DO/EO/US

Mitsuru SHIRAISHI, Masanori BABA, Yoshio ARAMAKI, Naoyuki KANZAKI, Osamu NISHIMURA

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

Copy of ISR and copies of Cited References

Copies of Forms 210 (ISR), 301, 304, 308, 332, and PCT/RO/101

Translation Cover Sheet, Copy of Front Page of International Appln., Itemized Return Postcard

Express Mail Label No. EL 916492262 US

Date of Deposit 12/12/01

U.S. APPLICATION NO. (if known, see 37 CFR 1.53) <b>10/018321</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP00/03879</b>		ATTORNEY'S DOCKET NUMBER <b>2614 US0P</b>	
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21. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... \$1040.00  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$890.00  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$740.00  International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$710.00  International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$100.00  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				<b>CALCULATIONS PTO USE ONLY</b>          <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: right;">\$ 890.00</td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: right;">\$</td> <td></td> </tr> </table>		\$ 890.00		\$	
\$ 890.00									
\$									
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: right;">\$</td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: right;">\$</td> <td></td> </tr> </table>		\$		\$	
\$									
\$									
CLAIMS *	NUMBER FILED	NUMBER EXTRA	RATE						
Total claims	37 - 20 =	17	x \$18.00	\$	306.00				
Independent claims	3 - 3 =	0	x \$84.00	\$	0				
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00	\$					
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	1,196.00				
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$					
<b>SUBTOTAL =</b>				\$	1,196.00				
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$					
<b>TOTAL NATIONAL FEE =</b>				\$	1,196.00				
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$					
<b>TOTAL FEES ENCLOSED =</b>				\$	1,196.00				
*After entry of Preliminary Amendment				Amount to be refunded:	\$				
				charged:	\$				

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 500799 in the amount of \$ 1,196.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 500799. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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 Takeda Pharmaceuticals North America, Inc.  
 Suite 500, 475 Half Day Road  
 Lincolnshire, IL 60069 USA  
 (847)383-3372 fax (847)383-3481

Elaine M Ramesh  
 SIGNATURE  
 Elaine M. Ramesh, PhD, JD  
 NAME  
 43,032  
 REGISTRATION NUMBER  
 For Customer No. 23,115

10018321.121201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	tba	Art Unit:	tba
Filed:	tba	Examiner:	tba
1 <sup>st</sup> Inventor:	Mitsuru SHIRAISHI	Allowed:	
For:	Benzazepine Derivative, Production and Use Thereof	Batch:	
Atty. Dkt. No.	2614 USOP	Paper No.:	1

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

**USPS EXPRESS MAIL LABEL. No. EL 916492262 US**

**DATE IN: December 12, 2001**

**Itemized Papers/Items:**

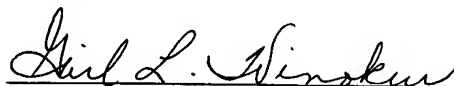
1. This Postcard (1 page) and Certificate of Express Mailing (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. Copy of Request form of the International Application PCT/JP00/03879, (Form PCT/RO/101)(5 pages)
4. English Translation of the International Application as filed in Japanese [This includes Specification total 550 pages, including Claims 1-37 (9 pages), Abstract (1 page)] and transmittal (1 page)
5. Preliminary Amendment (15 pages)k
6. Information Disclosure Statement (1 page) with Form PTO-1449 (1 page), and copies of references (3)
7. Copy of Forms PCT/IB/301, 304, 308 and 332 (4 pages)
8. Copy of the front page of the International Application as published (WO 00/76993) (1 page)
9. Declaration and Power of Attorney (5 pages)
10. Assignment (2 pages) and Assignment Recordation cover Sheet (1 page X 2)
11. Copy of International Search Report (2 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

BOX PCT  
Commissioner for Patents  
Washington, D.C. 20231.

on this date, 12/12/01

Dated: 12/12/01

  
Gail L. Winokur